CAUSE NO. D-1-GV-04-001286

THE STATE OF TEXAS	:	IN THE DISTRICT COURT OF
	:	
ex rel.	:	
	:	
VEN-A-CARE OF THE FLORIDA KEYS, INC.	:	
	:	
Plaintiffs,	:	TRAVIS COUNTY, TEXAS
	:	
v.	:	
	:	
ABBOTT LABORATORIES, INC., ABBOTT LABORATORIES, HOSPIRA, INC.,	:	
Defendants.	:	
	:	201ST JUDICIAL DISTRICT

EXPERT REPORT OF STEPHEN W. SCHONDELMEYER, PHARM.D., PH.D.

I. QUALIFICATIONS AND BACKGROUND

1. I make this statement as an independent expert in pharmacy, pharmaceutical economics, and public policy. I hold the following positions and titles in the College of Pharmacy at the University of Minnesota: Head, Department of Pharmaceutical Care & Health Systems; Century Mortar Club Endowed Chair in Pharmaceutical Management and Economics; Professor of Pharmaceutical Management and Economics; and Director of the PRIME Institute. I hold a Bachelor of Science in Pharmacy (1974, University of Missouri-Kansas City), a Doctor of Pharmacy and Residency Certificate (1977, University of Kentucky), a Master of Arts in Public Administration (1979, Ohio State

reimbursement or report false and misleading average manufacturer prices (AMPs) or best prices (BPs).

VI. THE TEXAS VENDOR DRUG PROGRAM

95. The Texas Vendor Drug Program (Texas VDP) spent about $253 million on pharmaceuticals in 1991. By 2005 Texas VDP drug spending had grown nearly ten-fold to $2.475 billion. The annual rate of growth in drug spending for Texas VDP was at double-digit rates for every year, but one, between 1991 and 2005. Texas served about 2.7 million Medicaid enrollees in 2003 and provided nearly 35 million prescriptions.

96. The Texas VDP approach to estimating drug acquisition cost was the object of a study I conducted with colleagues at Abt Associates, Inc. on behalf of CMS in 2005. [Wrobel, Schondelmeyer, et al., *Case Study of the Texas Vendor Drug Program,* 2005, p. 65.] A previous study had indicated that Texas VDP appeared to have a system for estimating acquisition cost that was very similar to the optimal system recommended by a panel of experts. [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, p. 29]

97. The case study of the Texas VDP drug pricing approach revealed the following distinctive features with respect to Texas' approach to estimating acquisition costs:

* Data were collected directly from manufacturers. Manufacturers were required to report prices as a condition for the inclusion of their products on the covered drug list for Medicaid and other state-funded outpatient drug programs.
* The VDP used a unique pricing concept. Its intent was to receive a current net market price. Manufacturers were responsible for reporting price changes and keeping the VDP's price data up-to-date.
* Data were reported by channel of distribution and class of trade. The VDP's EAC varied according to the channel of distribution used by the pharmacy to purchase a prescription drug—such as wholesaler, chain warehouse, or direct from the manufacturer.
* Several sources of market signal data were used to identify and correct pricing issues and problems.

* The drug price database used for setting payment amounts was created and maintained by the Texas VDP, rather than by an outside vendor, such as First DataBank.

98. One of the findings of this study was that list prices, whether AWP, WAC, or DP, are no longer a reliable basis for estimating acquisition costs for prescription drugs. This finding was "consistent across all three data sources: the interviews and documents, the drug price data, and the panel discussion. Sources also agreed that the extent of the discrepancy between list prices and acquisition costs varied according to a drug's patent status, with the discrepancy being greatest for generic drugs." [Wrobel, Schondelmeyer, et al., *Case Study of the Texas Vendor Drug Program,* 2005, p.64.] Both the interview respondents and the expert panel agreed that "collecting drug price data directly from manufacturers remained the most promising approach for establishing reliable estimated acquisition costs."

99. This study conducted for CMS concluded that the "Texas VDP was able to successfully collect data from manufacturers for all of the drugs covered by its Medicaid program and to construct a database for use in payment using that data. This in itself is a significant accomplishment." The conclusion went on to point out "A major challenge in implementing the Texas VDP price database has been ensuring that the prices submitted by manufacturers actually reflected the concept of current net market price by class of trade as requested by the Texas VDP data collection form." [Wrobel, Schondelmeyer, etal., *Case Study of the Texas Vendor Drug Program,* 2005, p.65.]

100. The Texas VDP approach to estimating acquisition cost based upon manufacturer reported drug prices that were current and generally available net prices paid by pharmacies in the market was considered to be the best, and most practical, method of estimating acquisition cost for purposes of determining appropriate

reimbursement under a state Medicaid drug program. However, the Texas VDP reimbursement process depended upon drug manufacturers to report prices that reasonably represented the actual net prices currently and generally paid by providers in the marketplace. [Deposition of Martha McNeill, July 12, 2007, p. 45, lines 19 to 24]

101. Abbott personnel recognized that Texas Medicaid was an excellent and well-run program. Michael Heggie stated in an internal Abbott memo that "Texas is a very very well run Medicaid program; perhaps the best in the country." [Memo from Michael Heggie to Pete Baker dated August 22, 1997 with a Subject: Vendor Drug program, TXABT 099273].

A. Prescription Reimbursement Under the Texas Vendor Drug Program

102. The Texas VDP reimbursement amount for prescription drugs provided through community pharmacies is set by a process known as a 'lower of' formula. That formula as described in the Medicaid regulations and reported in the NPC Medicaid Book [NPC, *Pharmaceutical Benefits*, 1993, p. 15., and other annual volumes] states drug reimbursement or payment "is not to exceed the lowest of":

- the maximum allowable cost (MAC) of the drug as established by HCFA's [now CMS's] pharmaceutical reimbursement board for certain multisource drugs (generic drugs), plus a reasonable dispensing fee;
- the estimated acquisition cost (EAC) of the drug (the price generally and currently paid by providers for a particular drug in the package size most frequently purchased by providers), as determined by the program agency, plus a reasonable dispensing fee; or
- the providers' usual and customary charge to the public for the drug.

103. CMS (formerly HCFA) regulations clearly state that the estimated acquisition cost is meant to be "as close as feasible to the price generally and currently paid by the provider. The states are, therefore, expected to set their ingredient cost levels as close as possible to actual acquisition cost." ["HHS Action Transmittal, HCFA-AT-77-113